REMARKS

Claims 1-130, 151, 152, 154 and 163-242 have been cancelled without prejudice or disclaimer; claims 131, 153, 155-157, 159 and 161 have been amended; and new claim 244 has been added, thereby leaving claims 131-150, 153, 155-162, 243 and 244 pending in the application. Support for the subject matter of claim 244 is found in cancelled claim 154. The specification has been amended to correctly describe U.S. Patent No. 4,690,134 to Snyders. The '134 patent is of record in this application. Reconsideration is respectfully requested in view of the following remarks.

Withdrawn Subject Matter

Withdrawn claims 132, 134-149, 156, 157 and 159-162 depend directly or ultimately from claim 131. In accordance with the provisions of M.P.E.P. § 821.04(a), Applicants respectfully request that the election of species requirement with respect to these claims be withdrawn and these claims be examined once claim 131 is found allowable.

Rejections Under 35 U.S.C. § 102

A. Claims 131, 133, 150-153 and 155 were rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 6,238,334 to Easterbrook et al. ("Easterbrook"). Claims 151 and 152 have been cancelled. The rejection is respectfully traversed.

Claim 131 has been amended to incorporate the features of claims 151, 152 and 154. As claim 154 is not included in this ground of rejection, claim 131 is patentable over Easterbrook. Thus, dependent claims 133, 150, 153 and 155 are

also patentable over Easterbrook. Therefore, withdrawal of the rejection over Easterbrook is respectfully requested.

B. Claims 131, 133, 150-153 and 155 were rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 5,971,910 to Tsitlik . The rejection is respectfully traversed.

As claim 154 is not included in this ground of rejection, claim 131 is also patentable over Tsitlik. Dependent claims 133, 150, 153 and 155 are also patentable over Tsitlik for at least the same reasons as those for which claim 131 is patentable. Therefore, withdrawal of the rejection over Tsitlik is respectfully requested.

C. Claims 131, 133, 150-153, 155 and 243 were rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 5,131,905 to Grooters. The rejection is respectfully traversed.

As claim 154 is not included in this ground of rejection, claim 131 is also patentable over Grooters. Thus, dependent claims 133, 150, 153 and 155 are also patentable over Grooters.

Claim 243 recites a process for assisting the function of a heart including a left ventricle, a right ventricle and an outer wall, the heart disposed within a patient. The recited process comprises, *inter alia*, exporting the at least one command instruction from the controller to assist the heart by effecting changes in volume of a drive fluid within a first cavity of variable volume corresponding to the left ventricle and a separate second cavity of variable volume corresponding to the right ventricle, the

first and second cavities together extending circumferentially completely around the outer wall (emphasis added). Applicants respectfully submit that Grooters fails to disclose a process for assisting the function of a heart that comprises every feature of claim 243.

Grooters discloses an external cardiac assist device. The Office asserts that Grooters discloses "a single continuous cavity of variable volume extending circumferentially completely around the outer wall of the heart (33) with two chamber (34 and 36, or 34 and 38 - depending on the needed assistance)." *See* the Office Action at numbered section (6). Applicants respectfully disagree with this assertion.

Figures 3 and 4 of Grooters illustrate a cardiac assist device 10 including a first chamber 34, second chamber 36 and third chamber 38 (column 2, lines 62-68). The first chamber 34 corresponds to the left ventricle 14, and the second chamber 36 and third chamber 38 correspond to the right ventricle 16. *See* Grooters at column 3, lines 4-7, and lines 14-17. Figure 4 shows that the first chamber 34 and second chamber 36 together extend circumferentially around only a portion of the outer wall of the heart. Figure 4 also shows that the first chamber 34 and third chamber 38 together extend circumferentially around only a portion of the outer wall of the heart. Thus, because Grooters, at the least, does not disclose "first and second cavities together extending circumferentially completely around the outer wall" (emphasis added), Grooters does not anticipate the process recited in claim 243. Therefore, withdrawal of the rejection over Grooters is respectfully requested.

Rejection Under 35 U.S.C. § 103

Claim 154 was rejected under 35 U.S.C. § 103(c) over Grooters in view of U.S. Patent No. 6,626,821 to Kung et al. ("Kung"). The rejection is respectfully traversed.

As discussed above, claim 131 now recites the features of claim 154. Claim 131 recites a process for assisting the function of a heart having an outer wall using a direct mechanical ventricular assistance apparatus, with said heart disposed within a patient. The claimed process comprises, *inter alia*, exporting said at least one command instruction from said controller to assist said heart by effecting changes in volume of a drive fluid within a single continuous cavity of variable volume of said direct mechanical ventricular assistance apparatus, said cavity extending circumferentially completely around said outer wall of said heart (emphasis added). It is respectfully submitted that the combination of Grooters and Kung does not suggest the process recited in Claim 131.

Grooters' cardiac assist device includes an inflatable space 33 in fluid communication with a liquid or gas supply hose 35. *See* column 2, lines 55-56, and Figures 3 and 4 of Grooters. Grooters discloses that "[s]pace 33 can be inflated such that membrane 32 completely engages the heart, thereby allowing device 10 to be used on various sized hearts. For example, on a large heart, space 33 is collapsed and on smaller hearts, space 33 is inflated accordingly." Grooters does not suggest assisting the heart 12 by effecting changes in volume of a drive fluid within space 33.

In contrast, Grooters discloses that the heart 12 is operatively connected to an EKG machine, which senses the QRS waves of the heart to activate the pump for

supplying fluid to compartments (chambers) 34, 36, 38 in timing with contractions of the heart (column 3, lines 48-52). Grooters further discloses that "[t]he extent of inflation of the chambers can be controlled and adjusted so as to provide the necessary degree of assistance to the cardiac contractions" (column 3, lines 54-57). Accordingly, Grooters discloses that inflation of the three distinct chambers 34, 36 and 38 is adjusted to provide the necessary degree of assistance to the cardiac contractions.

Kung does not cure the deficiencies of Grooters with respect to the process recited in claim 131. Kung discloses a flow-balanced cardiac wrap for enclosing a ventricular region of the heart. The embodiment of the cardiac wrap 110 shown, for example, in Figure 1 of Kung, includes numerous inflation elements 112 arranged in parallel longitudinally. Each individual inflation element 112 defines a separate cavity of variable volume, which is inflatable to apply pressure to the heart 100 on which the wrap 112 is fitted. Kung depicts other embodiments of the wrap in Figures 7-13, 19 and 23-25, for example. Each of these other disclosed embodiments also includes multiple inflation elements, each defining a separate cavity, such that each wrap includes multiple cavities. Kung does not disclose or suggest a wrap including a single continuous cavity of variable volume extending circumferentially completely around the wall of a heart, as recited in claim 131. Accordingly, because the combination of Grooters and Kung does not suggest every feature recited in claim 131, these references do not support the alleged *prima facie* case of obviousness. *See* M.P.E.P. § 2143.03

Therefore, withdrawal of the rejection over Grooters and Kung is respectfully requested.

Information Disclosure Statement Filed on June 21, 2006

At numbered sections (8) to (11) of the Office Action, the Examiner provides remarks regarding the Invention Disclosure Statement (IDS) filed on June 21, 2006. At numbered section (8), the Examiner refers to one reference that is an approximately 700 page book and another reference that is a 340 page book. It is Applicants' understanding that the Examiner's remarks pertain to Clive Rosendorf, "Essential Cardiology," pages 23-699 ("Rosendorf"); and Arthur T. Winfree, "When Time Breaks Down - The Three-Dimensional Dynamics of Electrochemical Waves and Cardiac Arrhymias," 340 pages ("Winfree"). Copies of these references were submitted with the IDS filed on June 21, 2006. These references were also cited in the Form PTO-1449 submitted with the IDS.

In the copy of the Form PTO-1449 attached to the Office Action, the Examiner's initials are provided for each cited reference. The Examiner's initials acknowledge that Rosendorf and Winfree were considered.

At numbered section (8), last two lines, the Examiner acknowledges that "there is no requirement to explain the materiality of the submitted references." However, at numbered section (9), the Examiner states "burying of a clearly relevant reference in a lengthy reference may not comply with the Applicant's duty of disclosure." At numbered section (11), the Examiner further states that:

> [I]t is recommended that if any information that has been cited by applicants in the above referenced information disclosure statements is known to be material for patentability as defined by 37 CFR 1.56, Applicant should present a concise statement as to the relevance of that/those particular documents therein cited.

Based on the Examiner's remarks at numbered sections (8) and (9) of the Office Action, it is Applicants' understanding that the Examiner has recommended

that Applicants submit a concise statement regarding the relevance of Rosendorf and Winfree, if these references are known by Applicants to be material for patentability as defined in 37 C.F.R. § 1.56.

In response to the Examiner's remarks and recommendation, Applicants provide the following remarks. The specification references to both Rosendorf and Winfree. In the present specification, Rosendorf is described in the paragraphs at page 19, lines 11-16; page 37, line 26 to page 38, line 21; and page 82, lines 7-11; and Winfree in the paragraph at page 100, line 28 to page 101, line 13. According to M.P.E.P. § 609.04(a)(III), a concise explanation of the relevance of information cited in an IDS may be provided as part of the specification.

Rosendorf and Winfree were cited in the June 21, 2006, IDS for the Examiner's consideration, as well as obtain written acknowledgement from the Office that the Examiner considered these references.

After receiving the Office Action, the undersigned consulted with the original author of the application, John Hammond, regarding Rosendorf and Winfree. The undersigned was informed that Rosendorf and Winfree were cited as background information in the present specification, and that portions of these references that pertain to the citations in the specification are the following:

1. Paragraph at page 19, lines 11-16: "Standard terminology is widely used in cardiac art." In Rosendorf, Chapter 3, "Ventricular Function," pages 38 - 57, is relevant to this description in that it defines or uses in context a substantial amount of standard cardiac terminology.

2. Paragraph at page 37, line 26 to page 38, line 21: "The use of such heart sounds in diagnosis of cardiovascular conditions is described in Chapter 7 of

the text *Essential Cardiolofy Principles and Practice*, C. Rosendorf, 2001 ... ." In Rosendorf, Chapter 7, "Physical Examination of the Heart and Circulation," pages 111-117, specifically provides this information.

3. Paragraph at page 82, lines 7-11: "Other arrangements of such electrodes will be apparent to those skilled in the art. Such arrangements may include those performed in standard practice of electrocardiography, which is described in ... *Essential Cardiology*, Clive Rosendorf ... ." In Rosendorf, Chapter 8, "Electrocardiography," pages 121-126, provides basic information on the location and significance of EKG leads.

4. Paragraph at page 100, line 28 to page 101, line 13: "Electrophysiology input **1542** includes ... three-dimensional data **1573**. ... With regard to three-dimensional data, reference may be had to, 'When Time Breaks Down - The Three-Dimensional Dynamics of Electrochemical Waves and Cardiac Arrhythmias,' Arthur T. Winfree ... ." In Winfree, Chapter 5, "A Clue Involving Space," pages 102-124, provides description and illustrations of certain types of three-dimensional electrophysiological data. Additionally, in Winfree, Chapter 8, pages 189-216, "Patterns of Timing in Three Dimensional Space," describes spatial patterns of timing in heart muscle, and applications of three-dimensional chemical reactions to electrophysiology.

Thus, those references were cited to afford context, support for certain technology, and to provide the reader with the resources for additional reading. Applicants are not aware of any more-material portions of those references. Further, as Applicants are not obligated to search the art, Applicants have not studied those

references for any more material teachings, but instead rely only on those portions discussed within the specification.

Conclusion

For the foregoing reasons, allowance of the application is respectfully requested. Should the Examiner have any questions concerning this response, to expedite prosecution, the Examiner is respectfully requested to contact the undersigned at the number given below.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: February 12, 2007

By: _____
Edward A. Brown
Registration No. 35,033

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620